

## REMARKS

The Examiner has maintained his restriction requirement between the non-elected claims 3, 4, 8, 9, 14 and 16 and claims 1,2,5-7,10-13, 15 and 17 on the ground that the elected species is a composition comprising heparin.

However, applicant respectfully traverses the Examiner's restriction requirement on the grounds that claim 1 calls for a composition including an agent which can be heparin, a dye or an antibiotic and is a generic claim. Once the generic claim is allowed all the remaining claims dependent thereon will also be allowable.

Accordingly, applicant traverses the Examiner's restriction requirement on the grounds that claim 1 is a generic claim and that upon allowance of claim 1 all the remaining claims dependent on claim 1 will be in condition for allowance.

In response to the Examiner's rejections to the drawings, applicant is submitting herewith a new set of drawings and sending a copy of same to the Chief Draftsman.

The substitute new drawings are believed to overcome the Examiner's objections to the originally filed drawings:

The Examiner's rejection of claim 1 under 35 U.S.C. §112 for failing to comply with the written description requirement, as this rejection may be attempted to be applied to the amended specification and claims, is respectfully traversed.

In support of this traverse, Applicant is submitting a PTO Form 1449, a check for \$180.00, and three references published prior to January 16, 2002, the filing date of this application, which describe various dendrimers that can be considered as specific dendrimers that existed at the time the application was filed.

The principle dendimer is a poly(amidoamine) dendrimer as set forth in the specification.

Further applicant submits three additional literature references published after the filing date of the application but making reference to previous developments of dendrimers prior to 2002 which can be included in the "specific dendrimers." The primary dendrimers known at the time of the filing of the subject application include poly(amidoamine) dendrimers, poly(propylene imine) dendrimers, polyether dendrimers, phenylacetylene dendrimers, chiral dendrimers,

and tecto dendrimers as described in the literature and as now set forth in the application which incorporates the dendrimer described in the application.

The state of the art indicates what dendrimers were variable to one skilled in the art at the time the application was filed as clearly set forth in the articles submitted herewith. Further, from a reading of the papers by the leading scientists in this field, namely, Tomalia, Vögtle, Newkome, Fréchet, and Balzani it is clear that preferred dendrimers would be PAMAM dendrimer which is referred to in the application. However, it has been noted that other dendrimers can also be utilized according to the teachings of the present invention.

Applicant does provide guidance that a preferred dendrimer is poly amidoamine.

As for quantity of experimentation, it is noted that the number of dendrimers is limited. See for example, the dendrimers listed in the Research Project: A. Hirsch; the types dendrimers described in the Technology White Paper; and the classification of dendrimers starting at page 3 in the article in the Express Pharma Pulse magazine.

Accordingly, applicant submits that the literature references cited herein clearly show that there would be no undue experimentation in choosing a dendrimer.

With respect to the Examiner's rejection of claim 1 under 35 U.S.C. §112, written description requirement, and with respect to the Examiner's rejection to claims 1, 2, 5-7, 10-13, and 17 under 35 U.S.C. §112, second paragraph as being indefinite for using the term "specific", applicant traverses this rejection as it may be attempted to be applied to the amended claims.

In support of this traverse, note the above remarks, the literature references, and note that applicant has deleted "specific" from claims 1, 10, 11, 12, and 15.

The Examiner's rejection of claims 1, 2, 5-7, 10-13, and 17 under 35 U.S.C. §103(a) for being unpatentable over the Zhong U.S. Patent No. 5,869,137 and the Matthews, et al. U.S. Patent No. 6,426,067 and further in view of the Karimi, et al. European Patent No. 0496305 (U.S. Patent No. 5,061,424) as this rejection may be attempted to be applied to the amended claims.

First, it is to be noted that applicant has amended claim 1 to call for dendrimers selected from the class consisting of poly(amidoamine dendrimers,

poly(propylene imine) dendrimers, polyether dendrimers, phenylacetylene dendrimers, chiral dendrimers, and tecto dendrimers.

Further, it is noted that Zhong is directed to coating a substrate with bio-active/bio-compatible coating substrate.

Zhong also teaches dipping a catheter into the coating composition set forth in Example 8.

It is also noted that Zhong teaches the uses of Hepburn components as one of the bio-active coatings.

However, Zhong does not teach the use of dendrimers as part of or in the coating.

While the Examiner contends that Matthews at column 12, lines 15 and 37, teaches compositions for preparing catheters, applicant can find no such teaching. In fact, at the places cited by the Examiner, lines 15 and 37 in column 12, applicant cannot even find the word catheter. A search of the Matthews, et al. patent revealed only one use of the word "catheter" in the patent and that is in column 8, at line 33. Here, reference to methods of administering the angiogenic inhibitor compounds is described as including other routes including "direct introduction such as with use of various catheters and balloon angioplasty devices..."

Thus, there is no teaching in Matthews, et al. to apply a dendrimer to a catheter or to provide a coating having dendrimers therein to the outer surface of a catheter. All that Matthews et al. teaches is the use of a dendrimer such as a PAMAM dendrimer as a carrier for angiogenic inhibitor compounds including various acid containing moieties.

All that the Karimi et al. reference, either the EP or the U.S. patent, discloses is a method for applying a lubricious coating to an article that can be a catheter.

Karimi et al. teaches a composition comprising a mixture of polyvinyl pyrrolidone and polyurethane for making a surface of a catheter lubricious. Applicant does not teach the use of polyvinyl pyrrolidone. Applicants only teaches the use of aliphatic polyurethane in their composition.

In summary, while Zhong teaches coating a substrate with a bio-active or bio-compatible coating which can include heparin and Matthews et al. teaches a dendrimer carrier for supplying an angiogenic inhibitor compound to a location or cell inside a human body and Karimi, et al. teaches applying a lubricious coating to

an article such as a catheter, none of these references individually or in combination, teach coating a medical device such a catheter with a composition including a dendrimer which carries an agent such as an antibiotic, heparin or dye.

In other words, while Zhong teaches coating a device such as a catheter with a bio-active material and Karimi, et al. teaches coating a catheter with a lubricious material none of them individually or in combination teach adding to the coating a dendrimer for containing a bio-active agent.

Further, while Matthews et al. teaches using a dendrimer as a carrier for a bio-active agent such as heparin into a location or cell in a body, Matthews, et al. no way suggests adding a dendrimer to the coating of Zhong and/or Karimi, et al.

Only applicant teaches the use of dendrimers in the coating and the use of the dendrimers in the coating can have the advantage of a slow or time release of the bio-active agent.

Accordingly, contrary to the Examiner's conjecture and asserted conclusions, applicant submits that it is not obvious to make a coating that includes aliphatic polyurethane, dendrimers and an agent such as heparin. Further, applicant submits that there is no motivation, incentive, direction or suggestion in the references to combine the teachings thereof to somehow come up with the applicant's claimed method for creating a coating for a medical device or the medical device created with the coating.

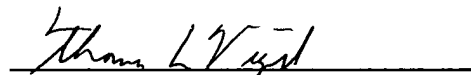
Applicant submits that upon reconsideration of the amended specification and claims and the above remarks it will be clear that the applicant's claimed method and medical device are not at all suggested by or taught by the prior art cited.

Applicant has made an earnest endeavor to place this application in condition for allowance and an early and favorable action to that end is requested.

Respectfully submitted,

December 29, 2003

Date



Thomas R. Vigil

Registration No. 24,542

WELSH & KATZ, LTD.

120 SOUTH RIVERSIDE PLAZA  
22<sup>nd</sup> Floor  
CHICAGO, IL 60606-3912  
Direct Telephone: 1-312-775-0407  
Telephone: 1-312-655-1500  
Fax: 1-312-655-1501  
Email: [trvigil@welshkatz.com](mailto:trvigil@welshkatz.com)